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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,947	12/24/2003	Kenji Fukuta	ONO-109	9577
35777	7590	05/31/2006	EXAMINER	
SHERMAN & ASSOCIATES 415 NORTH ALFRED STREET ALEXANDRIA, VA 22314			HUH, BENJAMIN	
			ART UNIT	PAPER NUMBER
			3767	
DATE MAILED: 05/31/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/743,947

Applicant(s)

FUKUTA ET AL.

Examiner

Benjamin Huh

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/18/05 & 7/26/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumura et al (US Pub. No. 2005/0070840A1) in view of Kedem et al (US Patent No. 4217200) and further in view of Theeuwes et al (US Patent No. 5169382). The Matsumura et al reference discloses an iontophoresis device that has an working electrode 11 connected to a medical instrument (13,14,15), consisting of a anion-exchange membrane & a cation-exchange membrane connected to a ionic medicine, and a counter electrode 21 connected to the working electrode 11 through a cell 3 and utilizes a electrolyte layer 12 to connect the working electrode 11 to a medical instrument (13,14,15). Now even though Matsumura does not explicitly disclose the medical instrument comprising a bag attention is directed to Theeuwes et al. The Theeuwes reference teaches an iontophoresis device that utilizes an ionic medicine which can be sealed in a bag, see col. 11 lines 41-47. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Matsumura et al with the device of Theeuwes in order to provide an efficient,

disposable, and/or interchangeable drug reservoir for use with iontophoresis. Now even though Matsumura does not explicitly disclose the use of utilizing an ion-exchange membrane bag attention is directed to Kedem. The Kedem reference teaches the use of anion-exchange membrane & cation-exchange membrane bags see col. 1 line 35 – col. 2 line 26. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Matsumura with the device of Kedem in order to provide a convenient disposable and/or interchangeable medical instrument.

With respect to claims 2 & 3, wherein the "... by melt-adhering ..." is deemed to be written in product by process language and since the bag is sealed it would inherently be able to have been sealed by that process, also it would be obvious for one of ordinary skill in the art to utilize melt-adhering to seal and form the bag since it is well known to do so not just in the medical art but also generally in sealing bags.

With respect to claim 4, wherein the ionic-medicine substance is a sheet impregnated with a solution of an ionic medicine, see para [00121] Matsumura.

With respect to claim 7, now even though the device of Matsumura does not explicitly disclose the use of a flexible armoring member for the electrodes attention is directed to Theeuwes. The Theeuwes reference teaches a flexible armoring member 22 in figure 1 on the device. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Matsumura with the device of Theeuwes in order to provide a flexible protecting member for protecting the components of the device from damage.

With respect to claims 8-9, wherein the electrolyte layer connects the working electrode to the medical instrument, see figures 3 & 4 Matsumura, and wherein the layer is in the form of a paste or a gel, see para [0122] Matsumura.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kedem et al (US Patent No. 4217200) in view of Theeuwes et al (US Patent No. 5169382). The Kedem reference discloses a medical instrument comprising a bag made of an ion-exchange membrane which can be heat sealed together and can be formed of an anion-exchange membrane and of a cation-exchange membrane, see col. 1 line 35 – col. 2 line 26. Now even though Kedem et al does not explicitly disclose the use of an ionic medicine or a sheet or a film impregnated with a solution of an ionic medicine used for iontophoresis attention is directed to Theeuwes et al. The Theeuwes et al reference teaches an iontophoresis device that utilizes an ionic medicine which can be sealed in a bag, see col. 11 lines 41-47. therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kedem with the device of Theeuwes in order to provide an efficient, disposable, and/or interchangeable drug reservoir for use with iontophoresis.

With respect to claims 2 & 3, wherein the "... by melt-adhering ..." is deemed to be written in product by process language and since the bag is sealed it would inherently be able to have been sealed by that process, also it would be obvious for one of ordinary skill in the art to utilize melt-adhering to seal and form the bag since it is well known to do so not just in the medical art but also generally in sealing bags.

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With respect to claim 4, wherein the ionic medicine-containing substance is a sheet or a film impregnated with a solution of an ionic medicine, it is well known in the art to impregnate an ionic medicine in a sheet or a film in order to provide a stable solid delivery form.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Li et al (US Pub. No. 2004/0112752A1) also discloses the prior art use of anion and cation exchange membranes as bags.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

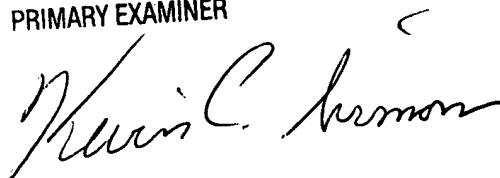
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN SIRMONS  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Kevin C. Sirmons", written in a cursive style.